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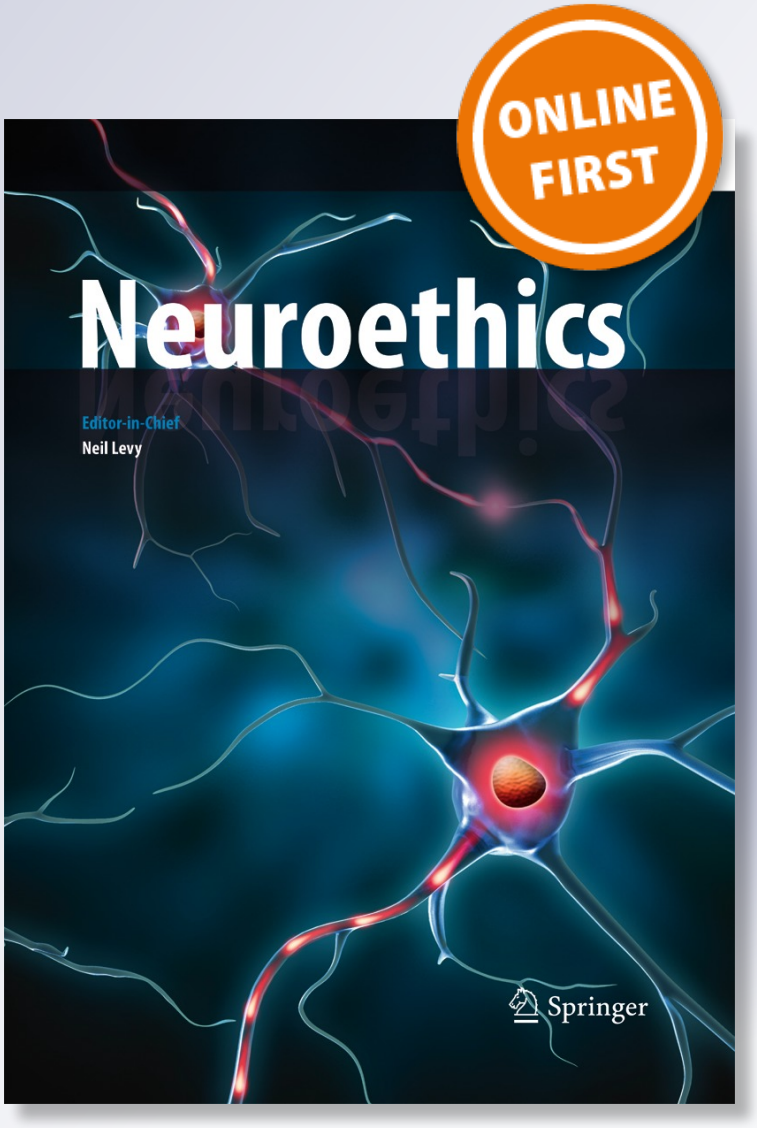

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ORIGINAL PAPER

Conflicts of Interest in Recommendations to Use Computerized Neuropsychological Tests to Manage Concussion in Professional Football Codes

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Abstract Neuroscience research has improved our understanding of the long term consequences of sports-related concussion, but ethical issues related to the prevention and management of concussion are an underdeveloped area of inquiry. This article exposes several examples of conflicts of interest that have arisen and been tolerated in the management of concussion in sport (particularly professional football codes) regarding the use of computerized neuropsychological (NP) tests for diagnosing concussion. Part 1 outlines how the recommendations of a series of global protocols for dealing with sports-related concussions (the 1st, 2nd and 3rd Consensus Statements on Concussion in Sport) have endorsed the use of NP testing. The development of these protocols has involved experts who have links with companies that sell computerised NP tests for concussion management. Part 2 describes how some professional football leagues—in particular the National Football League (NFL), the Australian Football League (AFL) and the National Rugby League (NRL)—have mandated specific NP testing products. They have done so on the basis of these international guidelines and by engaging experts who have conflicts of interest with NP testing companies. These decisions have also been taken despite evidence that casts doubt on the reliability and validity of NP tests when used in these ways.

Keywords Concussion · Sport · Conflict of interest · Chronic traumatic encephalopathy · Neuropsychological test · ImPACT · CogState · NFL · AFL · NRL

Introduction

Traumatic brain injuries are a major public health problem globally, and sport-related head injuries including concussion are a major contributor. The Centers for Disease Control has estimated that up to 3.8 million sports related concussions occur in the United States each year [1]. Concussion is a functional disturbance in the brain and may be the result of a fall (common in equestrian events, skiing and gymnastics) or head/body contact between participants (common in boxing and ice hockey). Some football codes exhibit high levels of risk of concussion because of repeated heavy collisions between participants. The prevalence of concussion in amateur and professional Australian Rules football [2] and rugby league [3] are among the highest of any contact sports. At the high school and collegiate level in the USA, American football has the highest participation rate among sports and the highest rate of concussion per thousand playing hours [1].

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Although concussion has often been regarded as an acute injury, post-mortem examinations of the brains of athletes who have suffered repeated head trauma on the playing field have found evidence of Chronic Traumatic Encephalopathy (CTE) [4–6]. CTE is a slow progressing degenerative brain disease that produces dementia like symptoms such as memory disturbances and speech problems. Other studies have suggested that multiple concussions may be associated with an increased risk of developing other chronic mental health problems such as depression [7]. To date more than three thousand former National Football League (NFL) players have filed lawsuits against the NFL claiming that their concussions were mismanaged and that the NFL concealed evidence of the long term health risks of playing.

It remains to be determined which athletes are at greatest risk of CTE, although the most severe cases identified to date have been linked to longer playing careers and higher levels of exposure to repeated head trauma [4]. While the post-mortem studies that have been conducted cannot say anything about the prevalence of CTE among athletes or footballers more generally, they do raise the prospect that athletes who sustain repeated concussive (and possibly sub-concussive) injuries in "collision sports" of all kinds (e.g. rugby league, Australian Rules football, ice hockey) are at increased risk of developing neurological problems later in life. Reflecting what has now become a highly controversial medical, legal and ethical issue one recent editorial claimed that "*the management of this one injury seems to provoke more debate than all other sports injuries combined*" [8].

Neuroscience, neuroimaging and neuropathology are progressing our understanding of the long term consequences of concussion, but the ethical issues related to concussion prevention and management are an underdeveloped area of inquiry. Recently, Valerio and Illes outlined potential ethical issues with the use of neuroimaging in concussion management and return-to-play guidelines [9], and Gilbert and Johnson have highlighted issues of consent and duty of care towards young athletes who participate in sports with a high risk of concussion [10]. Given that there are very large numbers of youth and amateur participants in various contact sports worldwide, a possible link between repeated head trauma (including concussion) and long term neurological harm has widespread ethical implications for parents, schools, and other caretakers.

Professional collision sports with high rates of concussion are laden with issues of ethical interest. The emergence of the now ubiquitous paid "team doctor" raises ethical issues such as confidentiality, patient autonomy, informed consent and the influence of third parties, all of which present difficult problems for sports medicine as a discipline in trying to prevent and manage injuries [11]. Often a central problem is raised by the competing interests that team doctors have in caring for athletes whilst having obligations as employees to coaches and owners who are in the business of winning games [12].

Those in charge of professional collision sports also have an uneasy relationship with concussion because they trade in a product that carries an inherent risk of head trauma. Although some rule modifications can make these sports safer (e.g. by prohibiting particularly dangerous ways of tackling), it is unlikely that concussions can be completely eliminated from American football, rugby league and Australian Rules football. Goldberg has pointed out that the NFL has tolerated a number of competing interests in the research, development and implementation of their concussion management policies, but argued that these reflect similar ethical issues that arise in the US health care system [13]. This article continues that theme by exposing several examples of conflicts of interest that have been tolerated in the management of concussion in sport at two levels—1) the formation of international guidelines on how to manage concussion in sport; and 2) the specific concussion management policies that have been implemented by some football leagues in light of these guidelines.

Conflicts of Interest

It is useful to begin by clarifying the nature of a "conflict of interest", explaining why such conflicts of interest are in need of regulation, and how their effects may be remedied. The "standard view" of conflict of interest put forward by Davis [14–16] describes a situation whereby a person *P* (e.g. a physician; a researcher) is in a relationship with another party (e.g. a patient; a committee) and is required by their role to exercise judgement on behalf of this party. In medicine the physician typically has a duty to advocate for the interests of their patients (or the public) [17]. *P* has a conflict of interest if they also have a "special interest"

that may potentially interfere with the proper exercise of their judgement in that relationship. According to Davis an interest is "*any influence, loyalty, concern, emotion, or other feature of a situation tending to make P's judgement (in that situation) less reliable than it would normally be"* [14, 16].

Davis' definition is similar to that of the Institute of Medicine [18] which encompasses classic examples of conflict of interest in many professions. For example in recent decades, the public has become increasingly aware of the special interests that many physicians have with the pharmaceutical industry as a result of payments, gifts, or other incentives that may affect physician's ability to exercise their judgement in the interests of their patient (or perhaps the public). Such links constitute a conflict of interest if they may potentially interfere with proper professional judgement about the interests of the patient. There is often a focus on personal financial gain as a special interest but, as Thompson [19] points out, this is because financial gain is a more objective and direct interest. Davis' definition also allows for a range of potential secondary interests that may affect judgement. The Institute of Medicine report on conflicts of interest echoes this noting that "*secondary interests may include not only financial gain but also the desire for professional advancement, recognition for personal achievement, and favours to friends and family or to students and colleagues" [18].*

Conflicts of interest do not necessarily have to affect professional judgement, but rather they must have a tendency to do so. Simply having a conflict of interest does not necessarily mean that a judgement has been influenced but without regulations to manage conflicts of interest it may be difficult to ascertain when special interests have improperly influenced a decision. Thompson [19] argues that the two primary reasons for regulating conflicts of interest are to maintain professional integrity and to maintain public confidence in professional judgement. The Institute of Medicine also argues that "*policies designed to reduce conflicts of interest and mitigate their impact provide an important foundation for public confidence in medical professionals and institutions*" [18].

In medical publishing, conflicts of interest are typically dealt with by: requiring authors to disclose any conflict; removing the special interest; or avoiding a conflict by distancing oneself from participation in the relationship [19]. Leading academic journals routinely require researchers and clinicians to disclose financial and non-financial relationships with third parties when publishing articles or developing guidelines on the grounds that links with interested parties (e.g. the pharmaceutical industry) may subtly influence study findings [20] and clinical recommendations [21].

Simply disclosing a conflict of interest does not necessarily resolve the problem. The tendency for biased judgement still exists, and is made known, but this is not always reassuring if we are left to wonder what (if any) influence the conflict had on judgement or research findings. It may be more appropriate in some situations to seek to remove or avoid the conflict.

One largely overlooked area of conflict of interest has been in the development of consensus guidelines to manage concussion in sport. Part 1 of this article outlines how the development of a series of global protocols for dealing with sports related concussions—the 1st, 2nd and 3rd Consensus Statements on Concussion in Sport [22–24]—have endorsed the use of NP testing and recommended that organised sports make use of these tests. Conflicts of interest arise because these recommendations have been made by committees whose members have included experts who have financial and professional links with companies that sell computerised neuropsychological (NP) tests for concussion management. Questions are raised about whether these experts' judgements about the value of NP testing have been unduly influenced by their special interests in NP testing companies. Of particular concern is the fact that these competing interests have often not been disclosed and in making these recommendations the consensus committees have given greater weight to research funded by NP testing companies than they have to independent evidence that raises doubts about the reliability and validity of these NP tests.

Part 2 describes how some professional football leagues—in particular the National Football League (NFL), the Australian Football League (AFL) and the National Rugby League (NRL)—have made it compulsory for their teams to use particular NP testing products. This action appears to have been taken on the basis of expert advice from clinicians and researchers who have special interests with NP testing companies. In addition to bringing these important ethical issues to attention, this paper aims to explore potential remedies to these conflicts of interest and to encourage a closer neuroethical examination of concussion management.

Part 1: Neuropsychological Tests for Concussion as "Best Practice"

In 2001 (Vienna), the first International Consensus Conference on Concussion in Sport (ICCCS) was held to address the problem of concussion [22]. It was organised by the International Ice Hockey Federation (IIHF), the Federation Internationale de Football Association Medical Assessment and Research Centre (FIFA, F-MARC), and the International Olympic Committee Medical Commission (IOC). An expert panel of mostly sports medicine physicians authored the 1st Consensus Statement. The 1st Consensus Statement and two updated Statements on concussion in sport (the 2nd developed in Prague, 2004 and the third in Zurich, 2008) were intended to be used by medical practitioners, health professionals, coaches, and lay people involved in the management of concussed athletes at all levels of sport; amateur, youth and professional. In line with Davis' [14] and Brody's [17] conditions for conflict of interest, the panel members were required to exercise their judgement (or advocate) to protect the interests of the large number of people who participate in sports at the professional, amateur and youth level.

Each iteration of these guidelines has supported the use of NP testing for concussion and they have been widely disseminated in the scientific literature [25]. Over the last decade, a number of companies have developed and marketed computerized products that claim to assess the neuropsychological effects of concussion in athletes and to assist physicians in managing these problems. Companies that own these tests include: ImPACT [26], CogState/Axon [27, 28], CNS Vital Signs [29], and Headminder [30].

The Guidelines propose that these NP tests (which focus primarily on memory and reaction time) should be used as follows: (1) a "baseline testing" of an athlete will be done at the start of a sporting season, and then (2) if a head injury occurs, the base line test will be compared to follow up testing to assess when an athlete has sufficiently recovered from their injury to return to playing. These tests are sold to elite teams and increasingly to the large numbers of amateur and youth participants in contact sport across the globe, with the aim of universal annual use (Axon's slogan is "Every athlete, every year") A 2011 presentation by CogState's Chief Executive Officer estimated the size of the concussion management market for its product to be in excess of US$150 m, per year [31].

There are five major ethical concerns about the way that the three Consensus Statements on concussion in sport have supported NP testing for concussion management:

1) Only industry funded studies are cited in the Consensus Statements as evidence in support of the value of NP tests for concussion;
2) The industry funding of these studies is not clearly disclosed in the consensus document;
3) Some panel members have had direct links to the companies that own these NP tests but these links have not always been declared in the consensus documents;
4) No mention has been made in these documents of non-industry funded research that raises doubts about the reliability and utility of these tests;
5) Panel members with links to NP testing companies have advised a number of professional sporting leagues in the USA and Australia to adopt these tests and these leagues have subsequently mandated the use of these NP tests for all players—most notably, the National Football League (NFL); the Australian Football League (AFL); and, the National Rugby League (NRL).

Cases of concussion can be difficult to diagnose. Indicative symptoms may include loss of consciousness, headache, dizziness, poor balance, memory problems, and slowed reaction time. These symptoms can last for a short time or extend over several days and occasionally weeks. The published version of the 1st Consensus Statement in the *British Journal of Sports Medicine (BJSM)* [22] asserted that:

> Neuropsychological testing in concussion has been shown to be of value and continues to contribute significant information in concussion evaluation
> NP testing is one of the cornerstones of concussion evaluation and contributes significantly to both understanding of the injury and management of the individual.

ImPACT and CogState/Axon have had a major influence on published research on NP testing for concussion by funding research on the validity, reliability and utility of their products. The authors of these publications have typically included employees or part-owners of the company, researchers who have received funding from the company, and researchers

who have served as paid consultants to the company. In the 1st Consensus Statement, the only sources of evidence cited in support of endorsing NP testing were two papers with industry affiliations and both co-authored by members of the expert panel: First, a paper co-authored by panel member Mark Lovell who is also a co-owner of NP testing company, ImPACT [32]. And secondly, an "*in press*" paper authored by two employees of CogState (an Australian NP testing company) [33]. The Cogstate NP product was developed in consultation with Paul McCrory, the then editor of the *BJSM*. McCrory also co-authored the 1st Consensus Statement, has continued to receive research support from CogState, and has co-authored numerous publications about the CogState product with employees of CogState.

In discussing conflicts of interests in the development of clinical practice guidelines, the Institute of Medicine wrote that "*a conflict of interest is not an actual occurrence of bias or a corrupt decision but, rather, a set of circumstances that past experience and other evidence have shown poses a risk that primary interests may be compromised by secondary interests*" [18]. The links that some panel members had with ImPACT and Cogstate could reasonably constitute "special interests" as outlined by Davis [14], the Institute of Medicine [18] and Brody [17] in that they may have a tendency to influence judgement about the value of NP testing (a judgement made on behalf of sportspeople). The panel members special interests with NP testing companies variously included: owning shares in the company, being employed by the company, and being the receipt on research support from the company to investigate their products.

How should these links be assessed? The direct receipt of income via ownership or employment (for example Lovell's co-ownership of ImPACT) is arguably a serious conflict of interest that increases the likelihood of undue influence, especially considering the extent of possible benefit to the person. The 1st Consensus Statement recommends that sporting leagues use NP tests as part of their concussion management strategies:

> Organised sport federations have access to and should attempt to employ such [NP] testing as appropriate. To maximise the clinical utility of such neuropsychological assessment, baseline testing is recommended [22].

Research funding may be considered a less severe special interest but one that nonetheless includes the potential for "*professional advancement*" [18]. Although it cannot be proven that the special interests of some panel members in fact influenced their judgements about the value of NP testing, the existence of these special interests certainly raises reasonable concerns about an appearance of bias that, if more widely known, could undermine public confidence in the guidelines. One of the co-authors of the 1st Consensus Statement later wrote that "*this is the first time that neuropsychological testing has been so strongly advocated in a concussion-in-sport consensus statement.*"[34] Can we be confident that a panel without these links would have also have concluded that the use of computerised NP testing should be such a cornerstone of concussion management that all organised sporting federations should routinely use these NP testing products?

According to the Institute of Medicine [18] conflict of interest policies "*are by their nature designed to avoid the need to investigate individual cases in this way*". That is, we do not necessarily need to examine the motives of the decision makers, or the validity of their decision, to have good reasons for managing conflicts of interest. In order to protect public trust in the integrity of the Consensus panel recommendation, it would have been desirable that these conflicts of interest had been declared but the 1st Consensus Statement did not include a declaration of conflict of interest for any of the panellists or authors [22].

Declaration of interests is only one limited way of ensuring transparency and managing conflicts of interest [18]. We argue that in this case it was insufficient. Pointing out a conflict of interest certainly does not imply that the panellists have been guilty of unethical or unprofessional conduct but nor does a declaration of a conflict of interest eliminate concern. Simply knowing about the links that some panel members have with NP testing companies would not reduce the likelihood that their judgement could be influenced. We believe that a more appropriate policy would have been to exclude anyone with links to NP tests from the consensus panel that produced guidelines on their use.

These issues also went largely unaddressed in the 2nd Consensus Statement which updated the recommendations of the Vienna conference in 2004 in Prague. NP testing was again described as a "cornerstone" of concussion management and this time four studies were

cited in support of the claim. Once again, all were industry funded or affiliated pieces of research and several panel members had links to these companies: three of the studies were co-authored by Lovell (co-owner of ImPACT and co-author of 1st and 2nd Consensus Statement) [32, 35, 36], and a fourth was the same paper co-authored by employees of CogState referred to in the 1st Consensus Statement [33]. This time the *BJSM* publication included the following competing interest statement:

> Dr. Lovell is a shareholder in ImPACT, a neuropsychological testing programme. No other author has any declared conflict of interest or concussion industry affiliation [23].

Lovell's links to ImPACT were rightly disclosed but it was still not made clear to readers that the company he part-owned was largely responsible for producing the evidence that the 2nd Consensus Statement referred to when endorsing NP testing. It is also curious that the lead author of the 2nd Consensus Statement (McCrory) did not disclose his professional links to CogState in the form of research support. Again, these links could reasonably be considered special interests that may have tended to influence judgement when advocating in the interests of sports people.

Dr. Lovell was not a member of the 3rd Consensus panel. The reasons were not given but presumably his financial ownership of ImPACT was seen as constituting a special interest that could have a tendency to influence judgement about the value of NP testing. This was a more appropriate method of dealing with that conflict of interest than a simple declaration.

No conflicts of interest were disclosed by any panel members for the 3rd Consensus Statement. Unlike its predecessors it included the following statement:

> A broad based non-government, non advocacy panel was assembled to give balanced, objective and knowledgeable attention to the topic. Panel members excluded anyone with scientific or commercial conflicts of interest and included researchers in clinical medicine, sports medicine, neuroscience, neuroimaging, athletic training and sports science [24].

As we argued above, special interests are not confined to persons with a direct ownership of interested companies. "Scientific or commercial conflicts of interest" could reasonably be thought to include research funding from an interested company or research funding from a professional sporting organisation that has a direct interest in the concussion management guidelines developed by the panel. But it appears that the panel contributing to the 3rd Consensus Statement did not regard such third party links as "special interests" that may influence judgement. For example, the first author of the 3rd Consensus Statement (McCrory) had elsewhere disclosed continuous research funding from CogState since 2001, but he did not disclose this on the 3rd Consensus Statement. While a declaration of such interests would be a minimum requirement, such a conflict of interest could arguably be avoided by his deciding not to participate in drafting the guidelines.

When developing clinical guidelines, assembling panels free of conflicts of interest may sometimes be difficult and the existence of conflicts of interest in similar panels are widespread in medicine. But the importance of transparency about conflicts of interest (financial or non-financial) is often overlooked. One recent study of Institute of Medicine guidelines found that fewer than half of these committees included information about members' conflicts of interest, and of those that did, more than two-thirds of committee chairpersons declared a conflict of interest [37]. A review of more than 300 Australian clinical practice guidelines between 2003 and 2007 found that nearly 80 % did not include any information about conflict of interest [38]. A more recent review of Australia's most prolific guideline producers found that 85 % had not published any information about their conflicts of interest [39].

Clearly the development of guidelines on concussion management in sport benefits from using the expertise of those who are most familiar with concussion management and with the tools available for its diagnosis and treatment. It is not surprising then that some concussion experts have links with computerised NP testing companies—as consultants and co-developers, employees, owners, developers of educational material, funded researchers, and co-authors. But since not all persons expert in managing concussion have such links, it would have been preferable if: experts with these links did not dominate the membership of these Consensus panels; and, at a minimum, the interests of members who did have such links were fully disclosed in the published recommendations.

Industry Funding of Computerised NP Testing Research

Nowhere in the 1st, 2nd or 3rd Consensus Statements on Concussion in Sport is there an acknowledgement that the evidence used to justify endorsement of NP testing consists solely of industry funded research. While there is not typically a specific journal requirement to include such an acknowledgement, in its absence interested industry bodies are able to subtly influence clinical recommendations. In the case of research about the value of NP testing for concussion, studies funded by ImPACT and CogState have (perhaps unsurprisingly) yielded results that were favourable to the use of their products in the management of sports related concussion.

Is there anything wrong with relying on industry funded research? A major concern is that research funded by a company may bias results in an expected or desired direction [17]. For example, systematic reviews comparing neutrally sponsored drug trials with those sponsored by the pharmaceutical industry have found that industry-funded trials are much more likely to favour the company's product [20]. Investigator bias may be even more likely to occur when the investigators include owners and employees of the funding company.

Other forms of potential bias may arise in industry funded research. Industry funding may direct the kinds of questions that are asked and tested, often with the future marketing of the product in mind. This may bias the literature towards publication of results that are favourable to the funder's product, as has been noted in the pharmaceutical field with selective publication of clinical trials on anti-depressants [40]. The fact that the 1st, 2nd and 3rd Consensus Statements referred only to industry funded evidence about the value of NP testing raises concerns that evidence favourable towards the use of particular NP products (ImPACT and CogState) unduly influenced the decision to recommend that NP should be central to concussion management.

In 2008, the 3rd Consensus Statement on Concussion in Sport also asserted that neuropsychological (NP) testing "*has been shown to be of clinical value and continues to contribute significant information in concussion evaluation*" [24]. This statement was supported by six studies—all were conducted by researchers who elsewhere have disclosed links to the NP testing companies ImPACT and CogState [33, 36, 41–44]. There was no citation or discussion of several reviews that had been published since the 2nd Consensus Statement in 2005 that raised concerns about the utility and reliability of these NP tests. For example, one study that assessed test-retest reliability of the CogState NP test reported "*lower reliabilities than were previously reported*" in papers co-authored by CogState employees. The authors also raised doubts about the ability of the CogState test to "*accurately identify cognitive changes in individuals with concussion*" [45]. A 2005 review of the clinical validity and utility of ImPACT, CogState and Headminder concluded that "*none meet criteria to warrant routine clinical application*" and that baseline testing with these products has not been shown to affect the risk of concussion [46]. A more recent review of the ImPACT product found that the rate of "false-positive" results was around 30–40 %—that is, incorrectly classifying a normal subject as impaired [47]. More worrying was the suggestion that the rate of false-negative results may be similar—this may present a much more serious problem as described by Randolph [47]:

> Given the relatively low sensitivity and poor reliability of this test, ImPACT is likely to have a "false negative" rate that is as high as the "false positive" rate. In this setting, a false negative would be classifying an athlete as recovered, when in fact he or she was still experiencing cognitive impairment secondary to concussion… To the extent that there is any risk of "premature" return-to-play, the determination of recovery based on the use of an instrument with such a high false negative rate may paradoxically increase risk, by returning athletes who might otherwise be withheld from play longer in the absence of such data.

This criticism calls into question the decision of the expert panel to endorse NP testing.

Brody [17] has argued that when it comes to research funded by the pharmaceutical industry, apologists "*see a world in which valuable new discoveries save lives*" whereas critics are increasingly concerned about "*new drugs that are less effectives and less safe than the marketing claims to be*". The situation is arguably analogous in regards to NP tests for concussion management: the Consensus panel who have been involved in developing NP tests can only see their potential benefits;

their critics would argue that this appraisal does not reflect the state of the evidence for the effectiveness of NP products, and so has been biased by the commercial interests of the Guidelines' authors.

What harms may arise from the use of NP tests for concussion management? One risk is that athletes will be given a false sense of security and be "passed fit" to continue participation in contact sports on the basis of a test that has not been sensitive enough to detect concussion related impairments. A more general concern is that players and coaches may be falsely reassured that concussion is being prevented when NP tests may fail to diagnosis its presence or accurately assess when an injured player is sufficiently recovered to resume playing.

Part 2: From Consensus Statement to League Policy—the Mandating of NP Testing Products

Sanctioned violence is undoubtedly part of the appeal of football for some (perhaps many) fans. Some leagues court such interest in the way that they promote their product (for example, the National Rugby League website highlights the "Top 5 big hits of the week"). There are also clear financial disincentives for professional football leagues to admit that anyone who plays their sport in the way it is intended may risk serious neurological problems. In addition to the threat of expensive lawsuits, there is a risk that sponsors may not want to be associated with a hazardous activity, that spectators will turn away if they come to believe that their favourite athletes are doing themselves long term harm, and that parents will no longer allow their children play in youth leagues.

In recent years the AFL and NRL have attempted to address these concerns by implementing concussion management guidelines that are largely based on the recommendations of the 3rd Consensus Statement (also known as the Zurich Statement) [24]. In doing so the links between NP testing companies and the expert panels that formulated the Consensus Statements (described in Part 1) have extended to the development of policies for these professional football leagues that involve the routine use of NP testing.

In Australia, the AFL's and NRL's concussion management guidelines (CMGs) are based on the 3rd (Zurich) Consensus Statement. The lead author of the Zurich Statement (McCrory, a former team doctor for a professional AFL team), has said that:

> In Australia, the Australian Football League (AFL) and National Rugby League have developed their own guidelines in line with international best practice (e.g., the Zurich concussion guidelines) and have been proactive in this regard [8].

In line with the endorsement of NP testing in the three Consensus Statements, the AFL, NRL and NFL have all mandated the use of particular NP testing products when managing concussion. The NRL has argued that the compulsory use of such products is an even more conservative approach to concussion than that recommended in the 3rd Consensus Statement. In response to an article by one of the authors in the *Medical Journal of Australia* [48], the Chief Medical Officer of the NRL stated [49] that :

> The NRL takes the treatment of concussion extremely seriously, and the guidelines on return to play are and have been based on the best available scientific evidence. The current guidelines on return to play are based on the consensus statement produced at the Third International Conference on Concussion in Sport held in Zurich in 2008. The NRL guidelines were upgraded in April 2011 and made even more precautionary than the consensus statement. Since that time, the guidelines have stated that any player diagnosed as having a concussion is not allowed to return to the field of play on the same day. Further, affected players are not allowed to return to training until they are asymptomatic and their results have returned to baseline on CogState testing.

This statement placed the compulsory use of the CogState product at the forefront of the NRL's concussion management policy. Other football leagues—the NFL and AFL—have established their own advisory committees to provide independent advice to the leagues on how to manage concussion. As with the Consensus Statements, some of these committee members also have conflicts of interest with NP testing companies. For example, the NFL has been criticized for mandating the use of the NP concussion testing product sold by ImPACT given that two of ImPACTS's co-owners were members of the NFL's traumatic brain injury committee (TBIC) that developed the league's concussion management procedures [13]. One of those committee members was Mark Lovell, who was also a co-author of the 1st

and 2nd Consensus Statements on concussion which endorsed the use of NP testing and urged sporting federations to use these products. In describing the NFL's concussion policies, Goldberg said in 2008:

> The neuropsychologist overseeing the testing programs for the NFL is Mark Lovell… Lovell, along with Joseph Maroon, team neurosurgeon for the Steelers, developed their own battery of neuropsychological tests named ImPACT. Lovell and Maroon are both officers in the corporation designed to market the software, named ImPACT Applications. Furthermore, Lovell and Maroon are both members of the NFL-TBIC, and, more problematically, the ImPACT software is the very program that will be used to conduct the mandated neuropsychological testing. Frankly, a more obvious conflict of interest would be difficult to find.

Members of the NFL's TBIC were asked to exercise their judgement about the best way to manage concussion, ideally by providing independent, expert advice on how the NFL could improve player safety. However, there was clearly the potential for their judgement to be unduly influenced because prominent members of the panel had a special interest with a third party (ImPACT) that stood to benefit from mandating use of their product. One might, for example, ask why the ImPACT product was chosen, rather than the CogState or Headminder? Why was a particular product mandated rather than "NP testing"?

In Australia, similar issues of conflict of interest have arisen in decisions by the AFL and NRL to mandate the use of the CogState/Axon NP test. Why would different professional sporting leagues mandate different NP testing products and both claim that this was "best practice"? The decision to mandate the CogState/Axon product seems to have followed a similar path to that described for the NFL—that is, it was made on the advice of experts who had research links to the company who also contributed to the 3rd Consensus Statement.

In August 2010, CogState (a publicly listed Australian company) launched Axon Sports—this was an independently staffed joint venture with a US investment company to market the latest version of CogState's NP test [50] CogState acquired 100 % ownership of Axon in August 2011, [51]. In October 2010, Axon announced that Dr. Paul McCrory had been appointed as a Neurologist and Sports Physician Consultant with the company. This is the McCrory who has received research support from CogState since 2001 and was lead author of the 3rd Consensus Statement [52]. Since then a number of McCrory's published papers on concussion have acknowledged funding from CogState (e.g. [53, 54]) but few have disclosed his consultation role with Axon Sports. In 2010, the AFL established a concussion working group (that included McCrory) with the aim of directing research on concussion in the league in order to "*consolidate the best practice approach*" to concussion [55].

In April 2011, the AFL adopted new concussion management guidelines for its upcoming season. These were co-authored by Dr. McCrory [56], and based largely on the recommendations of the 3rd Consensus Statement. Around the same time (March/April 2011), CogState/Axon announced that the AFL and NRL had both mandated the use of their NP product for all teams when conducting baseline and follow up testing for concussion [57]:

> The NRL concussion policy mandates use of CogState by all clubs, to be funded by the NRL. The NRL decision follows last week's announcement by the AFL to introduce new concussion management guidelines in which the AFL doctors also recommended use of CogState by all clubs.

Less than 6 months after Dr. McCrory was appointed as a consultant to Axon Sports (then 50 % owned by CogState), the AFL made it mandatory for all professional teams to use the CogState/Axon product. The NRL took longer than the AFL to implement new concussion management guidelines, but eventually adopted the same procedures [49] so all NRL teams must use the CogState product to manage concussion. An article on the NRL's website says that:

> Every player undergoes a CogState baseline test each year…Rugby league has based its procedures on the latest world research, the world conference on concussion in sport [the Zurich Consensus Statement] and it has enlisted the advice of recognised authorities including Dr. Paul McCrory [58].

It is of concern that these football leagues have tolerated the links that some of their advisors have with NP testing companies. It is worrisome from a

public health point of view that most published studies on the reliability and usefulness of these products have been funded by the companies who own and market the tests and co-authored by employees or consultants to the company. The advice of these concussion experts about the use of NP testing products may be well intentioned but can the AFL, NRL and NFL be sure that this advice was unbiased? It is unclear whether the AFL, NRL or NFL have any policies for dealing with conflicts of interest among its expert advisors.

The AFL, NRL and NFL are commercial organisations and as such are free to engage with other business entities. Choosing to contract an NP testing company would appear to be similar to most other business relationships that the leagues have. It is likely that if the leagues talk to a Nike consultant they expect to listen to a Nike advocate—talk to an employee or consultant of CogState or ImPACT and expect to have that NP testing product advocated. Is there anything wrong with this?

We believe that there is when an advocate purports to be acting as an expert advisor solely interested in protecting player welfare. We believe that many stakeholders in football leagues—players, coaches, fans, and youth and amateur participants—would rightly be concerned if they believed that advice about the best way to manage concussion may be influenced by third party professional, commercial or scientific interests. This concern is heightened by a decision announced in July 2011 that the major corporate sponsor of the AFL, Toyota, would cover the costs of baseline concussion testing for a large number of youth and amateur players:

> Toyota will provide the same CogState concussion testing used by AFL clubs to over 25,000 grassroots footballers as part of the Toyota Good for Footy program. Toyota will be working closely with Axon Sports—the exclusive concussion management system of the AFL—to roll-out baseline concussion testing to more than 130 clubs in the Toyota Good for Footy program [59].

This decision was made despite published evidence that casts doubt on the precision of these tests.

Conclusions

We argue that those affiliated with or funded by companies marketing NP tests for concussion should not have been involved in the development of concussion management guidelines that advocate the use of these tests. It is especially worrisome that the main evidence cited in support of the use of these tests has been provided by the companies who own them, and by researchers whose work was funded by these companies. As has been noted, conflicts of interest among expert panels is commonly encountered but expert panels can either avoid including researchers and clinicians who have such conflicts of interest or form expert panels that are as free from conflicts of interest as is possible.

Financial and professional conflicts of interest in the development of the concussion management policies of the NFL, AFL and NRL (and their mandating of particular computerized NP tests for concussion) could undermine public confidence that these policies have been adopted in the best interests of player safety. The Australian codes have cited their adoption of guidelines based on the Zurich Consensus Statement and the mandating of the CogState NP test [49] as indications of their interest in managing concussion. The leagues have also tolerated conflicts of interest among their advisors who have links with the company that sells the NP testing products that they recommend. They appear to be either unconcerned about or unaware of evidence that casts doubt on the validity and utility of NP tests.

The NRL and AFL argue that their mandating of the Cogstate/Axon product shows that they take concussion very seriously. This seems at odds with the sceptical stance their medical advisors have publicly taken towards the potential long term harms of concussion, in particular CTE. For example, the Chief Medical Officer of the NRL has expressed scepticism about the relevance of evidence of CTE in former American footballers to Australian rugby league players [60]:

> I think that we need to be pretty careful how we interpret the Boston stuff. The aim of their game [American football] is to actually crash into each other with their heads, so potentially players are being concussed. We don't have any such thing in our game.

Similar scepticism about CTE has been expressed by the Director of the AFL's Medical Officer's Association [61]:

> We've got no evidence to suggest that the condition we're seeing in America from multiple

> head knocks is akin to what we see in Australian football…We have no evidence that CTE is an issue, and the long-term brain damage that they're talking about in America may not exist in Australia.

By casting doubt on the validity of research about long term harms, and by rejecting any analogy between American football and rugby league or Australian Rules football, these medical officers have sought to reassure players and the public that concussion is managed appropriately and that there is no reason to be concerned about long terms harms. Both codes have a medico-legal interest in being seen to responsibly manage concussion to avoid the lawsuits like those that former NFL players have brought in the US. The suspicion is that mandating computerized NP testing products is designed to deflect future legal actions without changing the game in ways that may reduce risks of head collisions. The fact the decision to adopt these policies has been informed by experts with conflicts of interest with the NP testing companies should be a source of concern for players, fans, public health researchers, the medical community and to neuroethicists.

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